



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/CHMP/13690/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Rxulti

brexpiprazole

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Rxulti. The marketing authorisation holder for this medicinal product is Otsuka Pharmaceutical Netherlands B.V.

The CHMP adopted an extension to the existing indication as follows:²

RXULTI is indicated for the treatment of schizophrenia in adults **and adolescents aged 13 years and older**.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold

